FEB 0 5 2002

510(k) Summary for the Stöckert Instrumente GmbH Centrifugal Pump (SCP) K011838

1. SPONSOR

Stöckert Instrumente GmbH
Lindberghstrasse 25
D80939 München
Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
Telephone: 011 49 89 323 010
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Date Prepared: November14, 2001

2. DEVICE NAME

Proprietary Name: Stöckert Centrifugal Pump
Common/Usual Name: Centrifugal Pump
Classification Name: Cardiopulmonary bypass speed control device

3. PREDICATE DEVICES

- Jostra RotaFlow (K991864)
- Medtronic Bio-Medicus BioConsole 540/550 (Multiple)

4. DEVICE DESCRIPTION

The Stöckert Centrifugal Pump, developed to address the needs of the health care marketplace, consists of the following components:

- SCP Control Panel
- SCP Drive Unit
- Flow Probe
- Emergency Drive Unit

The SCP is designed to be used exclusively with the COBE® Revolution Disposable Pump Head and in connection with Stöckert S3 and SC Systems. The power supply voltage (24 V DC) as well as the CAN Bus connection is provided through a

connection cable. The SCP utilizes the battery backup power from the S3/SC System Uninterruptible Power Supply in case of mains power failure.

5. INTENDED USE

The Stöckert Centrifugal Pump (SCP) is a cardiopulmonary bypass speed control device is indicated for speed-controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less. The SCP has not been qualified through in vitro, in vivo, or clinical studies for long-term use as a bridge to transplant, pending recovery of the natural heart, or extracorporeal membrane oxygenation (ECMO) procedures.

6. PERFORMANCE TESTING

Testing submitted in this premarket notification consists of functional acceptance testing, electrical/mechanical safety (IEC60601-1), and electromagnetic compatibility (IEC60601-1-2), software verification and validation, ship testing, and battery life. Test results demonstrate that the SCP and associated software perform as intended.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Stöckert Instrumente GmbH claims equivalence to cited predicate devices based on equivalence in indications for use, operational characteristics, and technological characteristics. A side-by-side comparison of the SCP to the predicate devices is provided in the table below.

Side-by-Side Comparison of the SCP with Cited Predicate Devices

Characteristic	**Stöckert Centrifugal Pump**	**Medtronic BIO-MEDICUS 540/550**	**Jostra RotaFlow**
Indications for Use: Speed controlled pumping through the cardiopulmonary bypass circuit for durations of six hours or less	Yes	Yes	Yes
Design			
Mounting System	Mast	Console	Console
Magnetic Pump Head Coupling	Yes	Yes	Yes
Communication with heart lung machine	Yes	No	Yes
Battery	Uses Battery in HLM console	Yes	Yes
Data Output	via HLM	serial port	serial port

Characteristic	Stöckert Centrifugal Pump	Medtronic BIO-MEDICUS 540/550	Jostra RotaFlow
Operational Specifications			
RPM Range	0-3500 RPM	0-4500 RPM	0-5000 RPM
RPM Accuracy	± 10%	Not specified	± 20 RPM
RPM Display Resolution	1 RPM	Not specified	10 RPM
LPM Range	-10 LPM to +10.0 LPM	-2 to 9.99 LPM	0 to 9.9 LPM
LPM Accuracy	± 10 % or 0.1 LPM, whichever is greater	Not specified	0.1 LPM
LPM Resolution	0.01 LPM (Flow > 0) 0.1 LPM (Flow < 0)	Not specified	0.01 LPM
Controls and Displays			
RPM Control Method	incremental shaft encoder	potentiometer	potentiometer
LPM Control	Yes, in AutoFlow Mode	No	Yes, in LPM Control Mode
Remote Control for automatic clamp (optional)	Yes	No	Yes
Secondary RPM display	Yes, Bar display	Yes, Bar display	No
Secondary LPM display	Yes, Bar display	Yes, Bar display	No
Pressure display	Yes, value source from HLM	Yes, internal probe	No
Other displays	—	2 Timers	—
Level and Air Bubble Monitoring	Yes	No	Yes
Safety Features			
Low RPM protection	software detent Low RPM enable by key stroke	mechanical detent Low RPM enable by depressing the speed control knob	No detent Low RPM Alarm
Adjustable Alarms	High Flow, Low Flow, Negative Flow	Low Flow, High Flow	Low Flow, Low RPM, High RPM
Runaway Protection	Yes, at 1000 RPM higher	No	Yes, at 20% higher
Emergency Hand crank	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Helmut Höfl
Director, Quality Assurance and Regulatory Affairs
Stöckert Instrumente GmbH
Lindberghstrasse 25
D80939 München
Germany

Re: K011838
Trade Name: Stöckert Centrifugal Pump
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary bypass pump speed control
Regulatory Class: Class II (two)
Product Code: DWA
Dated: November 27, 2001
Received: November 28, 2001

Dear Mr. Höfl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011838

Device Name: Stöckert Centrifugal Pump (SCP)

Indications for Use:

The Stöckert Centrifugal Pump (SCP) is a cardiopulmonary bypass speed control device (*21 CFR 870.4380*) indicated for use exclusively with the COBE Revolution Pump Head, for speed-controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less.

The SCP has been qualified only for typical durations of six hours or less, appropriate to cardiopulmonary bypass procedures and has not been qualified through in vitro, in vivo, or clinical studies, for long term use as a bridge to transplant, pending recovery of the natural heart, or extracorporeal membrane oxygenation (ECMO) procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011838

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)